California Medical Device Recall Information

Recall Name
Medtronic Recalls SynchroMed II and SynchroMed EL Implantable Drug Infusion Pumps Due to Failure of Priming Bolus

Recall Date	Product Description	Recalling Firm	Recall Reason
06/03/13	Implantable Infusion Pumps • SynchroMed II • SynchroMed EL **External insulin pumps for diabetes are not affected.*	**Medtronic, Inc.** Minneapolis, MN	*There is potential for unintended delivery of drugs during the priming procedure. This could result in a drug overdose or drug under-dose which could lead to respiratory depression, coma, and death.*
Recall Class	**Product Identification**	**Distribution**	**Affected Dates**
I	SynchroMed II, **Model 8637** (20 ml or 40 ml reservoir size) SynchroMed EL Programmable Pump (10 ml or 18 ml reservoir size) **Models:** • **8626** • **8626L** • **8627** • **8627L**	**CA**, nationwide	Manufactured dates: May 1998 - June 2013. Distributed dates: April 1999 - June 2013.

FOR ADDITIONAL INFORMATION, PLEASE VISIT:

http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm359119.htm